IN THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF NEW YORK

In re: Methyl Tertiary Butyl Ether (MTBE) Products Liability Litigation

Master File No. 1:00 - 1898 MDL No. 1358 (SAS)

M21-88

This Document Relates to:

New Jersey Department of Environmental Protection, et al. v. Atlantic Richfield Co., et al.

No. 1:08-cv-00312-SAS

NON-PARTIES THE HAMNER INSTITUTES AND DAROL E. DODD'S MEMORANDUM IN OPPOSITION TO PLAINTIFFS' MOTION TO ENFORCE WAIVER AND DECLASSIFICATION PROVISIONS OF PROTECTIVE ORDERS

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Non-parties The Hamner Institutes (the "Hamner") and Darol E. Dodd, Ph.D, DABT ("Dr. Dodd") (collectively, the "Hamner Entities"), by and through undersigned counsel, respectfully submit this memorandum in opposition to *Plaintiffs' Motion to Enforce Waiver and Declassification Provisions of Protective Orders* ("Plaintiffs' Motion").

INTRODUCTION

The Hamner Entities, as subpoenaed non-parties, produced tens of thousands of documents in the above-captioned action between 2010 and 2012. Some, but not all, of these documents are classified as confidential pursuant to the *Stipulation and Protective Order* dated September 29, 2010 (the "**Protective Order**"), an Order to which Plaintiffs expressly agreed and stipulated. *See* Declaration of Scott E. Bayzle dated August 5, 2014 ("**Bayzle Decl.**"), Bayzle Decl., ¶3, Ex. A. Plaintiffs have had many of these documents for nearly four years (beginning with the 2010 production) and all of the documents since *at least* July of 2012 (the last of the productions). In the years following these productions, neither Plaintiffs, nor any other party to this action, objected to the confidentiality classifications under the Protective Order. Now, years later, Plaintiffs attempt to skirt the agreed-upon declassification procedure and seek to dissolve the Protective Order. Plaintiffs' Motion is without merit.

The Hamner Entities do not contend that <u>all</u> of the tens of thousands of pages of documents produced under the Protective Order are still confidential. Given the passage of time and the fact that the MTBE Study has now been released and published, some of these documents are no longer confidential and no longer require protection under the Protective Order. Nevertheless, this is not true for <u>all</u> documents produced by the Hamner Entities, as the various document productions contain, for example, confidential internal work product and other sensitive information. Plaintiffs' Motion does not contest this.

Counsel for the Hamner Entities recently received and reviewed a transcript of the status conference held before the Court on May 13, 2014, during which Plaintiffs' counsel, Mr. Axline, requested that the Protective Order be lifted and represented to the Court that he understood that the Hamner "has no objection to lifting it." Bayzle Decl., ¶4, Ex. B (p. 38, line 12). That representation was absolutely inaccurate. As Plaintiffs' counsel knew, counsel for the Hamner Entities notified Plaintiffs' counsel, in writing, *the week prior to the May 13, 2014 status conference*, that the Hamner Entities in fact objected to Plaintiffs' request to lift the Protective Order in its entirety. *Id.* at ¶4, Exs. C & D. Contrary to the misrepresentations of Plaintiffs' counsel, the Hamner Entities have consistently maintained that the Protective Order cannot be dissolved because some of the documents produced, even now, contain confidential information that requires continuing protection.

Indeed, prior to Plaintiffs filing their Motion, counsel for the Hamner Entities informed Plaintiffs' counsel that, while the Hamner Entities could not agree to a blanket dissolution of the Protective Order (because some documents contain information that continues to need protection), they would consider specific requests for declassification under Section 8 of the Order. Under that section, Plaintiffs were required to identify the documents, or at least categories of documents, that they contend "should not have been designated as 'Confidential'" or as to which the confidentiality has been waived, and to provide the basis for such contention. *Id.* at Ex. A, ¶ 8(a). For example, by letter dated June 23, 2014, counsel for the Hamner Entities informed Plaintiffs' counsel:

... [t]he Hamner cannot agree simply to dissolve the Protective Order in its entirety. The Hamner disclosed an enormous amount of information in accordance with the Protective Order and certainly believes that much of this information continues to need protection. We cannot expend further time and expense reviewing the entire prior document productions because of your blanket request. If you have a legitimate reason to contend that

there are certain documents that should no longer be subject to the Protective Order, we ask that you identify those documents by bates-number and inform us as to why you contend those specific documents should be declassified. This will afford The Hamner with a reasonable opportunity to consider your request.

Id., ¶5, Ex. E.

Plaintiffs, however, refused to comply with the procedures set forth in the Protective Order.

Plaintiffs stipulated that the confidentiality protection afforded to documents produced under the Protective Order would extend until and after the MDL litigation concluded. Bayzle Decl., Ex. A, Section 14 ("provisions of this Order shall not terminate at the conclusion of this action" and "[w]ithin thirty (30) days after final conclusion of all aspects of the last MDL 1358 lawsuit", all documents "shall be returned to counsel for The Hamner, or destroyed."). Plaintiffs further stipulated that, in the event they had an objection to the classification of a document under the Protective Order, they would use the procedure set forth in Section 8 of that Order, entitled "Declassification." Under that Section, to challenge the designation of a document produced under the Protective Order, Plaintiffs agreed to identify the document and inform the Hamner "in writing, of the basis" for the confidentiality challenge to that document. *Id.* at Ex. A, Section 8. Under this framework, the Hamner would have a reasonable opportunity to assess the confidentiality challenge and determine if it would agree to the declassification of that document. Yet, Plaintiffs neither identified any documents (by bates-number, general category, or otherwise) nor set forth any basis for their contention that any such documents were not properly denominated as "Confidential" or that the Hamner somehow waived their confidentiality. In fact, Plaintiffs do not directly challenge the confidentiality designation of any document or categories of documents. Instead, without analysis, Plaintiffs are broadly requesting that the Protective Order be dissolved and everything declassified.

Plaintiffs concede that the Protective Order does not present any hardship to them in this litigation. *See* Plaintiffs' Motion at p. 3 ("Plaintiffs are already free to use the Hamner Data in this litigation"). Rather, Plaintiffs take the unusual position of arguing that they somehow can step into the shoes of the United States Environmental Protection Agency ("EPA") and that the Protective Order should be dissolved because the EPA allegedly wants or needs the Hamner "data" in order to evaluate the MTBE Study. Even if Plaintiffs had standing to make such an argument for the EPA (and Plaintiffs have provided no authority in support of such standing), Plaintiffs' contention is unfounded.

In the event the EPA actually wants or needs to review any information from the Hamner Entities related to the MTBE Study, there are already defined procedures in place for the EPA to obtain any such documentation. The MTBE Study was GLP-compliant (*see* Declaration of Dr. Darol Dodd dated August 4, 2014 ("**Dodd Decl.**"), ¶5) in accordance with 40 C.F.R. § 792.1 *et seq.* ("Good Laboratory Practice"). The EPA, therefore, can obtain such information in a manner consistent with the approach outlined under the federal regulations. Consequently, the Hamner Entities do not understand why or how this is a matter that can be pursued by these Plaintiffs in this manner, in this proceeding. Moreover, in the Protective Order itself, Plaintiffs expressly agreed that "the Documents, deposition testimony, and information contained in the Documents shall be used only for preparation and trial of the above-styled action." Bayzle Decl., Ex. A, ¶ 12. The use of the documents now sought by Plaintiffs has nothing to do with this action and would violate the Protective Order. For all the reasons stated herein, Plaintiffs' Motion should be denied.

FACTUAL BACKGROUND

In response to Plaintiffs' subpoenas, the Hamner Entities produced tens of thousands of

¹ The Protective Order, at Paragraph 9, contemplates this very type of process.

pages of documents over the course of three years. Plaintiffs' Motion glosses over the nature of these productions and the documents which are at issue. For the convenience of the Court, the Hamner Entities provide a brief summary of the various productions as follows:

A. The Initial Productions Prior to the Release of the Final MTBE Study Report.

By an Order dated August 18, 2010 (the "8/18/2010 Order"), this Court ordered the Hamner to "produce any raw data from its MTBE study, the final report of the study when completed, and any communications between ExxonMobil and [the Hamner] relating to the study." *See* Bayzle Decl., Ex. F (8/18/2010 Order at pp. 11-12). The Court also ordered that the Hamner was <u>not</u> required "to turn over its *internal* communications or work product" because such disclosure would "risk impeding the freedom of thought essential to the scientific progress." *Id.* (Order at p. 12 (emphasis in original)).

In compliance, on September 29, 2010, the Hamner produced to Plaintiffs the raw data used to prepare its draft report for the MTBE Study (collectively, the "Critical Raw Data"). Bayzle Decl., ¶6; Dodd Decl., ¶7. This production constituted 1301 pages (bates-labelled HAM0001-HAM1301) and was marked subject to the Protective Order. Bayzle Decl., ¶6. At that time, counsel for the Hamner also provided Plaintiffs with a list of additional materials – including analytical chemistry records, animal clinical observations, environmental study records, certifications, and animal tissues (slides) – on-site at the Hamner pertaining to the MTBE Study. Plaintiffs' counsel was invited, on several occasions, to come to the Hamner to review and inspect such materials, but Plaintiffs' counsel never did so. *Id.* at ¶7, Ex. G.

On October 14, 2010, the Hamner produced to Plaintiffs the emails between it and ExxonMobil related to the MTBE Study (the "Hamner-Exxon Communications"). This

production was bates-labelled HAM1302-HAM2233 and these documents were marked subject to the Protective Order. Bayzle Decl., ¶8, Ex. H.

B. The Release of the MTBE Study Final Report.

On or about December 23, 2010, the MTBE Study Final Report (consisting of over 1800 pages including appendices) was completed by the Hamner and a copy was furnished to Plaintiffs' counsel. *See* Dodd Decl., ¶4; Bayzle Decl., ¶9, Ex. I. Contrary to the allegations in Plaintiffs' Motion, the Hamner Entities did <u>not</u> provide this Report to the EPA. Dodd Decl., ¶4. The Hamner Entities believe the Report was provided to the EPA by one or more of the Study's sponsors. *Id*.

C. Plaintiffs Receive Study Records And Electronic Database.

The Hamner maintained its study records and data for the MTBE Study in accordance EPA standards and regulations (collectively, the "Hamner Study Records"). See Dodd Decl., ¶6; 40 C.F.R. § 792.1 et seq. The Hamner Study Records in hard-copy format were, and are currently, maintained in approximately twenty (20) boxes at the Hamner and are comprised of approximately 30,000 pages.² Dodd Decl., ¶6. Plaintiffs received a copy of these hard-copy Hamner Study Records (bates-labelled STUDY07001-00001 through STUDY07001-29819) under the Protective Order. Additionally, the electronic Hamner Study Records were maintained in the Provantis electronic database, the data collection software program used by the Hamner to conduct the MTBE Study. Id. Plaintiffs subsequently received an Oracle database file which contained the data exported from Provantis under the Protective Order ("Electronic Data"). Bayzle Decl., ¶10, Ex. J. The Hamner Study Records have been, and are now, preserved under EPA standards. Dodd Decl., ¶6.

² This is in addition to the numerous animal wet tissue boxes and boxes containing tissue slides. Dodd Decl., ¶6.

D. The 2012 Production.

In 2012, Plaintiffs served Dr. Dodd with a deposition subpoena. *See* Bayzle Decl., Ex. K. That subpoena directed Dr. Dodd to produce, at his deposition, various categories of documents. *Id.* Counsel for the Hamner Entities objected to the production of documents containing confidential information absent the entry of an appropriate protective order. *Id.* at ¶11, Ex. L. Among the documents responsive to the subpoena were those that included confidential internal communications and work product pertaining to the MTBE Study, including unpublished and unreleased drafts. Dodd Decl., ¶10. There was much correspondence between counsel for the Hamner Entities and Plaintiffs' counsel regarding the need for confidentiality protection for certain documents in that production. Ultimately, Plaintiffs' counsel and counsel for the Hamner Entities agreed that such confidential documents would be produced subject to and under the protection of the existing Protective Order. Bayzle Decl., ¶12, Ex. M. Accordingly, some, but not all, of the documents were marked subject to the existing Protective Order. This production was bates-labelled DP00001-DP21266 (the "Dodd Production"). *Id.* at ¶13, Ex. N.

E. Disparaging Remarks In Plaintiffs' Motion.

Plaintiffs' Motion cites a number of so-called "facts" that they contend undermine the validity of the MTBE Study. Plaintiffs' "facts" are plucked from isolated portions of a few select emails, as to which Plaintiffs provide limited context, and some of which are left unexplained by witness testimony. The Study, and the conclusions derived from the data collected during the two-year experiment, cannot be evaluated or summarized in such an isolated and haphazard manner. While that may be the hallmark of a political process or public relations campaign tuned to an individual agenda, this is a scientific study, developed through rigorous analysis, and must be evaluated in accordance with an established scientific process. The Hamner Entities stand firmly behind the validity and soundness of the MTBE Study.

<u>ARGUMENT</u>

I. PLAINTIFFS' REQUEST TO DISSOLVE THE PROTECTIVE ORDER AND FOR A BLANKET DECLASSIFICATION OF EVERY DOCUMENT PRODUCED UNDER THAT ORDER – REGARDLESS OF THE CONFIDENTIAL NATURE OF ITS CONTENT – IS WITHOUT BASIS AND SHOULD BE DENIED.

Despite repeated requests by the Hamner Entities, Plaintiffs made no effort to follow the agreed-upon procedure to declassify documents as set forth in Section 8 of the Protective Order. Rather than identifying the document or documents that they contend were improperly labelled as "confidential," or as to which confidentiality was waived, and providing "in writing" the reasoning for their contention, which is their burden under Section 8, Plaintiffs simply offer sweeping generalizations and rhetoric suggesting that nothing should remain confidential and the Protective Order should be dissolved. Plaintiffs' Motion does not attempt to address the various categories of documents produced by the Hamner Entities or raise any specific challenges to the designations of confidentiality for those documents.

As noted above, given the passage of time and the fact that the MTBE Study has now been released, the Hamner Entities do not contend that each of the tens of thousands of pages of documents produced under the Protective order are still confidential today. However, many of these documents do in fact contain the Hamner's confidential internal work product and require continued protection. The Hamner Entities are not parties to this action, and their confidential internal work product, produced to Plaintiffs in response to third-party subpoenas, should be used only for purposes of this litigation and should otherwise be kept confidential in accordance with the terms of the Protective Order. Plaintiffs are certainly not entitled to a license to publish arbitrarily the Hamner Entities' confidential information, particularly after agreeing in the Protective Order that they would not do so. A complete dissolution of the Protective Order

would improperly and needlessly damage the professional and business interests of the Hamner Entities.

A. The Hamner Entities Agree That Some – But Not All - Documents Are No Longer Confidential.

Notwithstanding Plaintiffs' failure to utilize the procedures in Section 8 of the Protective Order, the Hamner Entities – in an attempt to narrow the issues before this Court in light of the immense volume of documents produced – have looked back at the general categories of documents produced under the Protective Order. The Hamner Entities agree that some, but not all, of documents produced under the Protective Order are no longer confidential and may be declassified. The documents and information that The Hamner Entities agree may be declassified are as follows (collectively, the "Declassified Documents"):

- All Critical Raw Data (HAM0001 through HAM1301). These documents contain the raw data used by the Hamner Entities to prepare the draft MTBE Study Report. Dodd Decl. at ¶7. Now that the Report has been released, the Hamner Entities no longer consider this data confidential. *Id.* at ¶8. Most, if not all, of the Critical Raw Data is summarized in the MTBE Study Report. *Id.*
- The Hamner Study Records (STUDY07001-00001 through STUDY07001-29819, as well as the Electronic Data). The Hamner Entities agree to declassify the Hamner Study Records. Now that the MTBE Study Report has been released, the Hamner Entities no longer consider these documents or data confidential. Dodd Decl. at ¶8. Most, if not all, of the information contained in the Hamner Study Records is summarized in the MTBE Study Report. *Id.*
- <u>Hamner-Exxon Communications</u> (HAM1302 through HAM2233). The Hamner Entities agree to declassify the Hamner-Exxon Communications. Now that the MTBE Study Report has been released, these external communications with Exxon are no longer confidential.

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³ Presumably, this may be the information to which Dr. Stine referred to in his deposition. *See Plaintiffs' Motion* at p. 3. The Hamner Entities are not parties to this case. No one affiliated with the Hamner was present for the deposition of Dr. Stine, who is not an employee of the Hamner. Dodd Decl. at ¶13.

These Declassified Documents include all of the data collected by the Hamner during the MTBE Study, and all data relied upon in the compilation and publication of MTBE Study Report, as well as the other study records used by the Hamner to conduct the MTBE Study. Dodd Decl., ¶9.

B. A Dissolution Of The Protective Order Is Inappropriate Because Some Documents Contain Information That Needs Continuing Protection.

There are documents produced by the Hamner Entities that continue to need confidentiality protection under the Protective Order. These include certain documents in the Dodd Production. As noted above, some, but not all, of the documents in the Dodd Production were produced subject to the Protective Order. Unlike the Declassified Documents (which contain the Study's data and external email communications between Exxon and the Hamner), the Dodd Production is replete with information that is maintained by the Hamner Entities as confidential. Dodd Decl., ¶10. Such documents include preliminary, unreleased drafts of the MTBE Study Report; preliminary, unreleased drafts of potential or prospective journal articles; internal and confidential work product; and internal and confidential deliberations among the scientists during the conduct of the Study, including their internal reviews, critiques, and self-evaluative processes, all of which are fundamental to the robust exchange of ideas in the scientific process. *Id.*

Plaintiffs' Motion fails to meaningfully address or challenge, in any way, the confidentiality designation of these documents in the Dodd Production, and Plaintiffs have not attempted to meet their burden under Section 8 of the Protective Order by setting forth "in

⁴ This includes, but is not limited to, analytical chemistry records, necropsy/histology/pathology records, animal clinical observations, animal feed/bedding records, animal room checklists, animal receipts, animal body weights, environmental records and environmental monitoring data, cage and rack rotations, room water quality reports, animal serology, and necropsy checklists. Dodd Decl. at ¶6.

writing" the basis for their confidentiality challenge with regard to these documents. As parties seeking to lift the Protective Order, Plaintiffs clearly bear the burden of establishing the propriety of such dissolution. See, e.g., H.L. Hayden Co. v. Siemens Med. Sys., Inc., 106 F.R.D. 551, 554 (S.D.N.Y. 1985) ("if the issuance of a protective order was supported by a showing of good cause, the burden of persuasion is typically placed on the party seeking modification"); Factory Mut. Ins. Co. v. Insteel Indus., 212 F.R.D. 301, 303 (M.D.N.C. 2002) (if protective order was originally issued on good cause, party seeking to vacate or modify that order bears the burden of establishing the propriety of such dissolution).

Plaintiffs' burden of persuasion is particularly elevated because they stipulated to the Protective Order at its entry. *See, e.g., Jochims v. Isuzu Motors*, 145 F.R.D. 499, 501 (S.D. Iowa 1992) ("there is general unanimity among the courts that where a party to [a] stipulated protective order seeks to modify that protective order, that party must demonstrate particular good cause in order to gain relief. . ."). "The courts' rationale for this standard is that a party which in good faith negotiates a stipulated protective order and then proceeds to produce documents pursuant to that protective order is entitled to the benefit of its bargain; namely, to rely upon the terms of the stipulated protective order." *Id.* at 501-502. *See also Geller v. Branic Int'l Realty Corp.*, 212 F.3d 734, 738 (2d Cir. 2000) (absent showing by the moving party of improvidence in grant of protective order, or some extraordinary circumstance or compelling need, witnesses should be entitled to rely on enforceability of a protective order). To challenge the confidentiality designation of a document under the stipulated Protective Order, Plaintiffs in

While Plaintiffs' Motion is styled a one to enforce "declassification provisions" of the Protective Order, Plaintiffs seek a blanket "declassification" of *everything* and the dissolution of the Protective Order. In communications with the Hamner Entities' counsel prior to filing their Motion, Plaintiffs' counsel confirmed that the purpose of their Motion was to dissolve the Order in its entirety. *See*, *e.g.*, Bayzle Decl., ¶14, Ex. O.

fact agreed to bear the burden to identify the specific document or documents at issue and inform the Hamner, "in writing, of the basis" for the confidentiality challenge. Bayzle Decl., ¶ Ex. A, Section 8.

Plaintiffs' Motion relies heavily on *Fosamax Prods. Liability Litig.*, No. 06-CV-1789, 2009 WL 2395899 (S.D.N.Y. Aug. 4, 2009) in contending the Hamner bears the burden to overcome the "presumption of admissibility." *Fosamax* is inapposite to Plaintiffs' Motion and actually provides further support for why the Protective Order should not be dissolved.

In *Fosamax*, the Court quashed a subpoena served on a scientist member of the National Academy of Sciences, who had analyzed and commented on a report regarding drug safety. As the Court explained, it prohibited the plaintiffs from taking any discovery from the scientist because allowing discovery "from a third party researcher risks chilling participation in beneficial public research. There is a serious danger that permitting discovery in these situations 'inevitably tend[s] to check the ardor and fearlessness of scholars, qualities at once so fragile and so indispensable for fruitful academic labor." *Id.* at *4 (quoting *Sweezy v. New Hampshire*, 354 U.S. 234, 262 (1957)) (internal citations omitted). In fact, this Court, in its 8/18/2010 Order, held that the need to protect the confidentiality "is at its peak" when it involves "the *internal communications or work product* of the research body – as revealing these discussions may discourage researchers from freely expressing positions that, although controversial, need to be tested." *See* Bayzle Decl., Ex. F (8/18/2010 Order at p. 10, emphasis in original).

The *Fosomax* case did not address the dissolution of a stipulated protective order already in place; rather, it concerned the showing required when a subpoenaed non-party seeks to prevent discovery altogether. Here, Plaintiffs were permitted to take discovery. Plaintiffs openly concede in their Motion, that they "already have the Hamner Data," that "Plaintiffs' experts

already have used that Data in forming their opinions," and that the Protective Order allows "Plaintiffs to use the Hamner Data" at trial. *See* Plaintiffs' Motion at p. 15. The Protective Order does not prevent Plaintiffs from using any of the Hamner Entities' documents for this litigation; rather, it simply prevents them using such materials for purposes *outside* the litigation.

What Fosomax does underscore, however, is that courts routinely and consistently recognize the need to protect, as confidential, a researchers' internal and confidential work product, the deliberations among the scientists, and scientists' preliminary draft reports. If researchers knew that their internal deliberations and the internal reviews, critiques, and selfevaluative processes could be subject to unfettered release into the public domain by potentially biased litigants in a civil action, which would of course be the end result of dissolving the Protective Order here, it would necessarily have a chilling effect on the candid exchange of views, critiques, and opinions of the scientific panel conducting the study. See also, e.g., Dow Chemical Co. v. Allen, 672 F.2d 1262, 1276 (7th Cir. 1982) (no discovery even permitted because researchers "with the knowledge throughout continuation of their studies that the fruits of their labors had been appropriated by and were being scrutinized by a not-unbiased third party ... carries the potential for chilling"); Plough, Inc. v. National Academy of Sciences, 530 A.2d 1152, 1157 (D.C. 1987) ("the courts, in order to prevent a chilling of the uninhibited conduct of ... scientific research, have recognized an interest in protecting from discovery the analyses, opinions, and conclusions drawn by researchers from their data"). As noted above, in its 8/18/2010 Order, this Court made a similar holding consistent with *Fosomax*.

Moreover, Plaintiffs' contention that they "intended the Protective Order[]" to extend confidentiality protection only until the release date of the MTBE Study is without basis. By its express terms, the Protective Order, to which Plaintiffs stipulated, extends until and after the

MDL litigation is concluded; such protection was clearly not intended to end at the Study's release date. See Bayzle Decl., Ex. A, Section 14 ("The provisions of this Order shall not terminate at the conclusion of this action. ..."). In fact, the vast majority of the documents disclosed under the Protective Order were produced long after the release of the MTBE Study in December of 2010. As set forth above, many documents were produced under the Protective Order, in 2012, in connection with Dr. Dodd's deposition. As a condition to that production being made without seeking additional protection from the Court, Plaintiffs' counsel expressly agreed that the confidential documents in the Dodd Production would be subject to and under the protection of the existing Protective Order. Bayzle Decl., ¶12, Ex. M. It is beyond disingenuous for Plaintiffs to now suggest that they did not intend the Protective Order to continue in effect past the release date of the Study.

In sum, while the Hamner Entities agree that some documents are no longer confidential and can be declassified, many documents continue to need confidentiality protection to this day. Accordingly, Plaintiffs' request for dissolution of the Protective Order and a blanket declassification of all documents should be denied.

II. THE EXHIBITS TO DR. DODD'S DEPOSITION MARKED UNDER THE PROTECTIVE ORDER HAVE NOT BEEN DECLASSIFIED.

Two years after Dr. Dodd's deposition, Plaintiffs now contend, for the first time, that the exhibits to Dr. Dodd's deposition – which were marked as "HAMNER-CONFIDENTIAL" (in accordance with Paragraph 3 of the Protective Order) when produced and which are marked as "HAMNER-CONFIDENTIAL" in the official exhibits provided by the court reporter – have somehow become declassified because they were not re-marked, for a second time, as "HAMNER-CONFIDENTIAL" after the deposition. This argument is specious.

Dr. Dodd's deposition subpoena directed Dr. Dodd to produce, at his deposition, various categories of documents. Dr. Dodd's deposition commenced on July 27, 2012. Bayzle Decl., ¶ 15. In accordance with this Court's Suggested Rules of Discovery Practice No. 7, the Hamner Entities produced the Dodd Production on July 12, 2012, at least ten (10) days prior to the noticed deposition. *Id.* at ¶13. Some, but not all, of the Dodd Production was stamped as "HAMNER-CONFIDENTIAL" in accordance with Paragraph 3 of the Protective Order (*id.*) and, thus, became subject to the Protective Order.

Some of documents produced as "HAMNER-CONFIDENTIAL" for the deposition were in fact used as exhibits in Dr. Dodd's deposition. As used in the deposition, the copies of these exhibits continued to bear the "HAMNER-CONFIDENTIAL" stamp (*id.* at ¶15) and, thus, continued to be subject to the Protective Order. When the deposition was completed, and the court reporter provided the official copy of the exhibits, these exhibits bore the "HAMNER-CONFIDENTIAL" stamp. *Id. See* also Dodd Decl., ¶11.

Plaintiffs apparently contend that, after the deposition concluded and the exhibits were provided by the court reporter, the Hamner Entities had to then mark the exhibits, once again, as "HAMNER-CONFIDENTIAL." This makes no sense. The official deposition exhibits provided by the court reporter were already so marked. *Id.* at ¶15. The Protective Order does not provide that an exhibit, in order to remain subject to the Protective Order after a deposition, must bear two (2) separate "HAMNER-CONFIDENTIAL" stamps.

The Hamner Entities are not parties to the litigation and, as such, do not know what exhibits were marked as confidential in the depositions of other MTBE litigation deponents, including that of Dr. Willson at Experimental Pathology Laboratory, and have not reviewed any of those deposition transcripts (nor have they been afforded any opportunity to do so). Needless

to say, the Hamner Entities have certainly not waived their rights as to such matters since they received no notice, did not participate in, and were in fact unware of what transpired.

III. DEFINED PROCEDURES UNDER FEDERAL REGULATIONS ARE ALREADY IN PLACE FOR THE EPA TO FULLY REVIEW AND EVALUATE THE MTBE STUDY.

In their Motion, Plaintiffs contend that the Hamner Entities are somehow hiding or "withholding the [MTBE Study] Data from [the] EPA" and that the Protective Order should be lifted in its entirety so that EPA can have access to the Study data. See Plaintiffs' Motion at p. 11. Plaintiffs' disparaging contentions are untrue and without any merit.

First, the EPA has <u>not</u> requested any information or documentation from the Hamner Entities related to the MTBE Study. Dodd Decl., ¶12. Similarly, the Hamner Entities have not been informed of any such request by the EPA to any party to this litigation (or to anyone else). *Id.* Plaintiffs' Motion is void of any competent evidence whatsoever supporting their contention that the EPA has made a request for such information to anyone.

Second, the MTBE Study is GLP-compliant (*see* Dodd Decl., ¶5-6, 13) in accordance with the regulations of the EPA set forth in 40 C.F.R. § 792.1 *et seq.* If the EPA wants or needs information from the Hamner Entities related to the MTBE Study, there are defined procedures in place for the EPA to seek such information under federal regulations. Specifically, 40 C.F.R. § 792.15 provides the EPA with a mechanism to obtain, inspect, and review "all records and specimens required to be maintained regarding studies to which this party applies." 40 C.F.R. § 792.190 sets out the records required to be maintained, which are subject to review under the procedures. These records include, but are not limited to, all "raw data, documentation, records,

⁶ As an initial matter, Plaintiffs' Motion is void of any authority supporting the proposition that Plaintiffs have standing to assert any arguments or positions on behalf of the EPA in this manner and in this private litigation.

protocols, specimens, and final reports generated as a result of a study" Consequently, in the event the EPA needs any additional information from the Hamner Entities related to the MTBE Study, then the EPA would obtain such information in a manner consistent with the approach set forth in its applicable federal regulations.

The Hamner Entities have not hidden, and are not hiding, the MTBE Study data from any entity, including the EPA or other regulatory agencies. All data from the MTBE Study has either already been provided to the EPA or, as set forth above, is no longer confidential and is contained in the Declassified Documents. The extensive MTBE Study Report, along with all Declassified Documents, would enable a toxicology researcher in this field, including the toxicologists at the EPA, to fully evaluate the MTBE Study, including assessing the interpretation of, and conclusions drawn from, the data collected during the Study. The MTBE Study Report (including its appendices), as well as the Declassified Documents, set out the Study's conclusions and interpretations, and all the data upon which such conclusions and interpretations were based. Dodd. Decl., ¶9.

Contrary to the groundless comments in Plaintiffs' Motion, the Hamner Entities are not withholding the data underlying the Study's conclusions. Researchers in the field (including the scientists at the EPA) are equipped with all the information necessary to fully evaluate the MTBE Study and determine whether they agree or disagree with its conclusions. In fact, this evaluation has already taken place in the scientific community, as the MTBE Study underwent peer review prior to its publication.⁷ There have been articles published in other journals about

⁷ See Dodd, D., G. Willson, H. Parkinson, and E. Bermudez. *Two-year drinking water carcinogenicity study of methyl tertiary-butyl ether (MTBE) in Wistar rats.* J. APPL. TOXICOL. 33:593-606 (2013). *See also* Bermudez, E., G. Willson, H. Parkinson, and D. Dodd. *Toxicity of methyl tertiary-butyl ether (MTBE) following exposure of Wistar rats for 13 weeks or one year via drinking water.* J. APPL. TOXICOL. 32:687-706 (2012).

the MTBE Study, including at least one article that is critical of the MTBE Study and was

submitted by someone who is apparently working with Plaintiffs in this litigation, and the MTBE

Study has been the subject of discussion in the scientific community.

These discussions and reviews undermine Plaintiffs' arguments that the EPA is so

unsophisticated and divorced from the scientific discourse on MTBE that Plaintiffs have to take

it upon themselves to explain various points so that the EPA can "understand" what subjects to

review. Notwithstanding Plaintiffs' arguments to the contrary (see Plaintiffs' Motion at p. 16),

the EPA is fully capable and competent, and has the resources and procedures, in order to obtain,

review, and evaluate the appropriate Study data and the Study's conclusions.

Finally, as set forth in the Protective Order, Plaintiffs expressly agreed to use the

documents produced by the Hamner Entities, as non-parties to this action, only for the

preparation and trial of this action, and not for any other purpose. Bayzle Decl., Ex. A ¶ 12.

Accordingly, their current proposal, years after the fact, is in flagrant disregard of their prior

agreement and this Court's prior order.

CONCLUSION

For all the reasons stated above, the Hamner Entities respectively request that this Court

deny Plaintiffs' Motion.

Dated: New York, New York

August 6, 2014

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